

MINUTES - TB PROGRAM

PUBLIC WORKSHOP MEETING

VIDEOCONFERENCE: Las Vegas, Nevada, Carson City, Nevada and Reno, Nevada

March 21, 2006 @ 1:00 p.m.

Darcie Carpenter opened the meeting by reading the standard statement about the purpose of this workshop.

The purpose of this workshop is to provide an opportunity to the public to assist the agency in formulating a revision to existing regulations. The draft regulations will then be subject to a public hearing rulemaking process conducted by the State Board of Health. Testimony and written materials submitted during this workshop will be considered during the development phase. In the event your recommendations are not included in the proposed draft of the regulations, you may also present materials or testimony for consideration by the State Board of Health. Written materials should be submitted to:

Alex Haartz, MPH, Secretary
State Board of Health
Nevada State Health Division
505 E. King Street, Room 201
Carson City, NV 89710

Materials submitted 15 working days prior to a meeting of the Board for which this item will appear on the agenda will be included in the packets sent to the Board for their review.

Darcie Carpenter stated that at this time the plan is to submit this material to the State Board of Health for the June 16th meeting.

Darcie Carpenter opened the floor for testimony for or against these proposed amendments to the Nevada Administrative Code 441A.

Testimony from Clark County

Dr. Timothy Deneau, Medical Director for Occupational Health Services for Sierra Health Service in Southern Nevada, stated that Sierra Health Services is currently performing single blood assays using QuantiFERON Gold TB testing on its employees as a result of the variance to current regulations as granted by the State Board of Health. He stated that they currently test approximately 1800 health care employees annually and he added that their positive rate of skin testing has been reduced by approximately 40 to 50% as a result of using single blood assay.

The single blood test collection does cause a reduction in unnecessary follow-up x-rays, lost productivity and physical examinations and Sierra Health Services has estimated a cost savings of \$250,000 in the first two years of the use of this test. Sierra Health Services has found that there are several advantages to using the blood assay, the first being it is a single blood test vs.

up to four visits that can occur when you use a 2-step skin test. This results in much less time away from work for our health care workers resulting in cost savings and lost productivity. Sierra Health Services has found that the test results of blood assays are very objective and they are not subject to errors in interpretation or errors in inconsistency of placing the tests and even in inconsistency of patient self-reading of test results. Sierra Health Services found that the test results are independent of previous skin test results and have no bearing on previous BCG administration. The test provides exceptional sensitivity and specificity and effectively eliminates false-positives that have been seen with skin testing. As a result there is a lot less follow-up testing and treatment as we are seeing fewer false-positive than with the skin tests. Sierra Health Services has not found any disadvantage of using this test and pointed out that the Food and Drug Administration has approved this test and the Centers for Disease Control and Prevention has endorsed it for TB testing of health care workers. We fully support the adoption of these changes.

Penny Williams, for Quest Diagnostics stated she agreed with Dr. Deneau testimony. She added that the use of QuantiFERON would add in getting new employees on board quicker and that the test is not subjective as compared to the Mantoux skin test. Quest Diagnostics supports the change in the regulations.

Testimony from Carson City

Carson City had nothing to report.

Testimony from Washoe County

Dr. Mary Anderson, Health Officer, Washoe County District Health Department stated that for the record she was going to read a statement she sent to Mr. Haartz that morning.

That statement in full, is attached at the end of this document as a part of the Minutes.

Candy Hunter from Washoe County District Health Department, TB Program, was standing in for Diane Freedman who was unable to be there. She does have testimony that basically supports QuantiFERON Gold as did the physician in Clark County.

That statement in full, is attached at the end of this document as a part of the Minutes.

Last testimony ended at 1:20 p.m. Linda Anderson, Deputy Attorney General, recommended keeping the meeting open until 1:30 p.m. for any additional testimony.

Mary Ellen Harrell, Public Health Nurse Manager, Communicable Disease at Southern Nevada Health District indicated the Southern Nevada Health District supports the change in these regulations.

Brian Labus from Southern Nevada Health District suggested that all the references in 441.200 be updated to the most recent edition since the regulations are being revised, specifically 441.200 (e) which refers to the 1997 edition of the Red Book.



DISTRICT HEALTH DEPARTMENT

March 23, 2006

Darcie Carpenter, PhD
Nevada State Health Division
505 E. King Street, Room 103
Carson City, Nevada 89701

RE: Proposed Revisions to NAC 441A – Tuberculosis

Dear Dr. Carpenter:

Based upon your request to Ms. Candy Hunter, Community and Clinical Health Supervisor, enclosed is a copy of my letter to Mr. Haartz, and Ms. Diane Freedman's written comments addressed to Ms. Deborah McBride, Chief of the Bureau of Community Health, regarding the proposed revisions to NAC 441A (Tuberculosis).

Staff of the District Health Department appreciated the opportunity to present not only comments in support of the revisions, but also to voice the concerns regarding those revisions and to offer alternatives.

Should you have any questions please feel free to contact Ms. Hunter at 328-3750 or Ms. Freedman at 785-4787.

Respectfully,

M. A. Anderson, M.D., M.P.H.
District Health Officer

/jbs

Enclosures



RECEIVED

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HEALTH DIVISION
ADMINISTRATOR

DISTRICT HEALTH DEPARTMENT

March 21, 2006

Alex Haartz
Administrator
Nevada State Health Division
505 E. King Street, Room 201
Carson City, NV 89701

Re: Proposed Revisions to NAC 441A – Tuberculosis

Dear Mr. Haartz:

I have reviewed the proposed changes to NAC 441A relative to tuberculosis. I would like to express two concerns and suggest some modified language that would address each.

First, in light of the availability of new technology that offers an alternative to the Mantoux tuberculin skin test, I concur with the proposal to broaden the language in such a way that new tests can be utilized. I am concerned, however, that the proposed language may be too broad. When the first generation blood assays for mycobacterium tuberculosis (e.g., QuantiFERON) became available they were not recommended by CDC to replace the Mantoux method. I think it is possible that we will see other new tests become available that may not be appropriate for use within the context of public health. The proposed language does not require tests to be approved by the FDA nor does it require that they be recommended by CDC. The CDC guidelines that are adopted by reference do not adequately cover all instances in which the language has been changed.

In light of the above, I would suggest that you consider substituting the phrase "tuberculosis screening test approved by the FDA and recommended by the CDC" for each occurrence of the phrase "tuberculosis screening test."

Second, I am concerned with the changes proposed in NAC 441A.375(3b) and NAC 441A.380(2c) that remove the requirement for annual tuberculosis screening for healthcare facility staff and patients and substitute a risk-based frequency for screening. There does not appear to be any proposed language that specifically identifies who will

be responsible for conducting the risk assessment that will be used to determine screening frequency. I do not believe it would be appropriate to expect the healthcare facilities themselves to carry out this function nor do I think it reasonable to pass this responsibility along to local health authorities without additional funding.

I see two possible solutions to this concern. You could either add language that would specify the Bureau of Licensure and Certification as the entity responsible for performing the risk assessment in accordance with CDC guidelines or you could leave the default frequency at once per year unless an optional risk assessment performed by the facility, the local health authority, or the Bureau of Licensure and Certification suggests the need for more frequent screening. I cannot foresee any circumstance in which it would be appropriate for a healthcare facility to screen less frequently than once each year.

Thank you for the opportunity to review and provide comment on these proposed changes to NAC 441A.

Sincerely,

A handwritten signature in black ink, appearing to read "M. A. Anderson", followed by a horizontal flourish line.

M. A. Anderson, MD, MPH
District Health Officer

Deborah McBride, Chief
Bureau of Community Health
Nevada State Health Division
505 E. King Street, Rm. 103
Carson City, NV 89701-4797

I respectfully request approval of the NAC 441.A statute changes supporting the use of QuantiFERON –TB Gold

Use of this blood test for the presence of Mycobacterium tuberculosis infection is endorsed by the Center for Disease Control.

This test eliminates the frequent confusion regarding a false positive skin test due to previous vaccination with BCG or a truly positive skin test despite vaccination with BCG.

Because this test is more specific for M.tb, it will be useful to ensure those who are infected receive treatment to prevent progression to TB disease. And those who are not infected do not receive inappropriate treatment due to a false positive skin test. This will be especially useful when there is a question of TB infection in a child. Children are at a greater risk of developing active disease if infected than adults. Many children from endemic countries receive BCG vaccination. QuantiFERON – TB Gold test will provide a definitive answer so that children who are infected may be appropriately treated.

Respectfully submitted,

Diane Freedman, RN PHN - TB Coordinator
Washoe County District Health Department
Tuberculosis Prevention and Control Program
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